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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,540	09/22/2003	Lawrence M. Boyd	1842-0024	9957

28078 7590 06/22/2006

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SUITE 3250
INDIANAPOLIS, IN 46204

EXAMINER

PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/667,540	Applicant(s) BOYD ET AL.	
	Examiner Pedro Philogene	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/10/03, 9/2/05, 2/7/06, 4/7/06</u> | 6) <input type="checkbox"/> Other: _____ |

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33-91 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-42 of U.S. Patent No. 7,004,945. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that all the elements of claims 33-91 are to be found in claims 1, 17,22 (as they encompass claims 6,14,32, 36-39). The difference between claims 33-91 of the application and claims 1,17,22 of the patent lies in the fact that the patent claims include many more elements and are thus much more specific. Thus the invention of claims 1,17,22 of the patent is in effect a "species" of the "generic" invention of claims 33-91. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the application are anticipated by the claims of the patent, they are not patentably distinct.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33-42,45-64, 66-76,78-82,84-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Ray (WO99/02214).

With respect to claims 54,66, 73, 80, Ray disclose a device for sealably introducing fluent material directly into a disc space through an opening formed through the annulus fibrosis of the disc, comprising a seal (24) for cooperatively engaging the annulus fibrosis adjacent the opening for sealing the opening; and a tube (20) having a passage (as best seen in FIG.1, for the flow of fluent material therethrough, the tube being configured for cooperative sealed engagement through the seal; as set forth in page 11, lines 20-22; page 12, lines 1-16. the device (FIG.2) for distracting two adjacent vertebral bodies defining a disc space therebetween and for delivering a flowable material into the disc space, comprising a body including a proximal portion and opposite distal portion defining a shape (separable balloon shape) adapted to distract the disc space, and a first longitudinal passageway; as best seen in FIG.1, extending through the body and defining a first opening in the distal portion opening in the disc space; as best seen in Fig.2; injection device, as best seen in FIG.4.

With respect to claims 55-64, 67-76, 78, 79, 81, 82, 84-91, Ray discloses all the limitations, as set forth in page 11, lines 20-22, page 12, lines 1-16, page 14, lines 15-2, page 15, lines 13-18, page 17, lines 20-22, page 18, lines 1-14.

With respect to claims 33-42, 45-53, the method steps, as set forth, would have been inherently carried out in the operation of the device, as set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43, 44, 65, 83, are rejected under 35 U.S.C. 103(a) as being unpatentable over Ray (WO99/02214) in view of Fischer et al. (4,114,329).

It is noted that Ray did not teach of a vent extending through the cannula; as claimed by applicant. However, in the injector art, Fischer et al. evidences the use of a vent opening in a clearance or space so as to permit escape of air displaced by the material from the clearance or space and to prevent such escape of the material.

Therefore, given the teaching of Fischer et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Ray, as taught by Fischer et al. to permit escape of air displaced by the material from the clearance or space and to prevent such escape of the material.

Conclusion

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

5,800,549	9-1998	Bao et al.
6,443,988	9-2002	Felt et al.
6,506,214	1-2003	Gross
6,641,587	11-2003	Scribner et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pedro Philogene
June 20, 2006


PEDRO PHILOGENE
PRIMARY EXAMINER